

EXHIBIT 4

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15 NOVO NORDISK INC.

16 UNITED STATES DISTRICT COURT
17 SOUTHERN DISTRICT OF CALIFORNIA

18 In Re: INCRETIN-BASED
19 THERAPIES PRODUCTS
LIABILITY LITIGATION,

20 *As to All Related and Member Cases*

Case No. 3:13-md-02452-AJB-MDD

**DEFENDANT NOVO NORDISK
INC.'S OBJECTIONS AND
RESPONSES TO PLAINTIFFS'
GENERAL CAUSATION
REQUESTS TO PRODUCE TO
DEFENDANT NOVO NORDISK,
INC.**

Judge: Hon. Anthony J. Battaglia
Magistrate: Hon. Mitchell D. Dembin

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26 Defendant Novo Nordisk Inc. ("NNI"), for itself alone and for no other
27 defendant, pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure,

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1 hereby objects and responds to Plaintiffs' General Causation Requests to Produce
2 to Defendant Novo Nordisk Inc. as follows:

3 **PRELIMINARY STATEMENT**

4 In accordance with F.R.C.P. 26 and Case Management Orders entered in this
5 litigation, including the ESI Order, NNI has undertaken a reasonable search for
6 documents responsive to these Requests. In addition to any documents or
7 information referenced below in the responses to these Requests, NNI will produce
8 non-privileged responsive documents from the custodial files for the key custodians
9 relevant to general causation issues using agreed-upon search terms to cull
10 documents from these custodians. Those key custodians are:

- 11 (1) Michelle Thompson, Senior Director – Regulatory Affairs –
12 Therapeutic Area;
- 13 (2) Jason H. Brett, M.D., Senior Medical Director – Medical Affairs
14 Diabetes;
- 15 (3) Alan C. Moses, M.D., Senior Vice President and Global Chief Medical
16 Officer;
- 17 (4) Kathryn A. Owen, Vice President – Clinical Trial Management;
- 18 (5) Michael Sacco, Senior Director – Product Safety;
- 19 (6) Liselotte ("Lotte") Bjerre Knudsen, Ph.D., Senior Principal Scientist –
20 Diabetes Pharmacology & Bioanalysis; and
- 21 (7) Yizhen Xu, M.D., Ph.D., Director – Clinical Research.

22 **GENERAL OBJECTIONS**

23 1. NNI is willing to discuss any of the following Objections and
24 Responses in order to resolve disputes or provide clarification to the Responses
25 below.

26 2. NNI objects to Plaintiffs' "Definitions and Instructions" to the extent
27 such definitions and instructions, as incorporated into the Requests, render the
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1 Requests vague, ambiguous, overly broad, unduly burdensome, and not
2 reasonably calculated to lead to the discovery of admissible evidence.

3 3. NNI objects to these Requests to the extent they seek documents or
4 information protected by the attorney-client privilege, the attorney work-product
5 doctrine, the consulting expert exemption, the exemption protecting
6 communications passing between agents of a party conducting an investigation in
7 connection with litigation, or any other applicable privilege or exemption from
8 discovery. The inadvertent production of any document protected by privilege, or
9 the production of which is otherwise objected to in these responses and
10 objections, is not intended to constitute, and shall not constitute, a waiver in
11 whole or in part of such privilege or objection.

12 4. NNI objects to the Requests to the extent they seek confidential,
13 proprietary, competitively sensitive or trade secret information. To the extent
14 NNI produces responsive and non-privileged documents, any such documents that
15 contain confidential, proprietary, competitively sensitive and/or trade secret
16 information will be produced in accordance with the agreed-upon and Court-
17 ordered Protective Order entered in these cases.

18 5. NNI objects to the Requests to the extent they seek third-party
19 private, confidential, proprietary, competitively sensitive or trade secret
20 information which information has been maintained in confidence and may be
21 subject to contractual or court-ordered limitations on disclosure. To the extent
22 NNI produces such information, it will be produced in accordance with the
23 agreed-upon and Court-ordered Protective Order entered in this litigation.

24 6. NNI objects to the Requests to the extent responsive information
25 may be subject to the limitations of foreign privacy laws or other applicable laws.
26 NNI objects to the Requests to the extent they seek patient information that is
27 required to be withheld by state, federal, and/or foreign law, including, but not
28 limited to, 21 C.F.R. § 20.63(f).

1 7. NNI objects to the Requests to the extent they contract, expand, or
2 otherwise interfere with the rights and duties of the parties under the existing
3 Orders, including, but not limited to, Case Management Orders, Pre-Trial Orders,
4 and Minute Orders, governing this litigation.

5 8. NNI objects to these Requests to the extent they seek documents
6 related to foreign regulatory submissions, requirements, or activities, or the
7 direction of foreign regulatory bodies, other than the EMA, as described herein,
8 because such documents are neither relevant nor reasonably calculated to led to
9 the discovery of admissible evidence and are unduly burdensome to produce.
10 Such information is subject to different regulatory and legal standards and
11 requirements, and can be influenced by political, cultural, and social differences,
12 including, but not limited to, differences in the practice of medicine. NNI agrees
13 to produce the EMA regulatory communications and submissions files for
14 Victoza® only under the unique and specific facts of this case, namely, that NNI
15 relies upon the EMA's July 2013 Assessment and the FDA and EMA's February
16 2014 Assessment as it relates to general causation. NNI maintains its position
17 that regulatory filings with foreign agencies are irrelevant to product liability
18 actions in the United States and should not generally be produced in these
19 litigations.

20 9. Any response to a Request shall not be construed as a concession or
21 admission that any response, testimony, or document related thereto is relevant or
22 otherwise admissible in this action, nor shall any response constitute or be
23 construed as a waiver of any objection to the admissibility of such response,
24 testimony, or document related thereto.

25 10. The foregoing General Objections are specifically and expressly
26 incorporated in each and every one of the Responses herein and the reassertion or
27 specification of any of these General Objections or the assertion of other
28 objections in no way implies a failure to assert each and every General Objection.

1 **REQUESTS TO PRODUCE**

2 **REQUEST NO. 1:**

3 The DOCUMENTS identified in YOUR answers to Plaintiffs' General
4 Causation Interrogatories to Defendant Novo Nordisk, Inc.

5 **RESPONSE TO REQUEST NO. 1:**

6 NNI incorporates, as if fully set forth herein, the General Objections by
7 reference. NNI objects to this Request as overly broad, vague, and ambiguous.
8 NNI further objects to this Request to the extent it seeks confidential, proprietary,
9 competitively sensitive, or trade secret information. To the extent NNI produces
10 responsive and non-privileged documents, any such documents that contain
11 confidential, proprietary, competitively sensitive, and/or trade secret information
12 will be produced in accordance with the agreed-upon and Court-ordered Protective
13 Order entered in these cases.

14 Subject to and without waiving or otherwise limiting the foregoing General
15 and Specific objections, NNI will produce non-privileged documents responsive to
16 this Request, as specified in NNI's responses to Plaintiffs' General Causation
17 Interrogatories and more fully below, and in accordance with the deadlines ordered
18 by the Court.

19 **REQUEST NO. 2:**

20 The IND/NDA and any SNDAs for VICTOZA in native electronic
21 searchable format as maintained by YOU.

22 **RESPONSE TO REQUEST NO. 2:**

23 NNI incorporates, as if fully set forth herein, the General Objections by
24 reference. Subject to and without limiting or otherwise waiving the foregoing
25 General Objections, NNI refers Plaintiffs to its production of IND and NDA files
26 dated through February 28, 2014, produced at Bates-ranges NNI-IND-61040-
27 00000001 – NNI-IND-61040-00060258 and NNI-NDA-22341-00000001 – NNI-
28 NDA-22341-01384489. NNI's production includes SNDAs for Victoza®. NNI

1 further states that the IND and NDA productions have been produced in accordance
2 with the agreed-upon November 15, 2013 ESI Order, with an index and in a
3 searchable format.

4 **REQUEST NO. 3:**

5 All other correspondence, data and other DOCUMENTS that YOU provided
6 to or received from the FDA related to the safety of VICTOZA with respect to
7 pancreatitis and/or pancreatic cancer, which are not part of the IND/NDA or any
8 SNDA for VICTOZA.

9 **RESPONSE TO REQUEST NO. 3:**

10 NNI incorporates, as if fully set forth herein, the General Objections by
11 reference. NNI further objects to this Request as overly broad and unduly
12 burdensome to the extent it seeks “all” correspondence, data, and documents.

13 Subject to and without waiving or otherwise limiting the foregoing General
14 and Specific objections, NNI states that it maintains IND and NDA files, which
15 are the official repositories for communications with and submissions to the FDA
16 regarding the safety of Victoza®. NNI produced its IND and NDA files and
17 refers Plaintiffs to its response to Request No. 2.

18 **PERSONS WITH DISCOVERABLE INFORMATION**
19 **ON GENERAL CAUSATION ISSUES**

20 **REQUEST NO. 4:**

21 Corporate organization charts that identify the persons with supervisory
22 responsibility over scientific research into the safety of VICTOZA and those
23 working at their direction; the persons responsible for determining whether
24 VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer and those
25 working at their direction; the persons in charge of compiling and reporting
26 pancreatitis and/or pancreatic cancer ADVERSE EVENTS for VICTOZA and those
27 working at their direction; and the persons in charge of maintaining the source

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DOCUMENTS for pancreatitis and/or pancreatic cancer ADVERSE EVENTS for VICTOZA and those working at their direction.

RESPONSE TO REQUEST NO. 4:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Request because it fails to define certain terms and phrases, including “supervisory” and “in charge.” NNI further objects to this Request to the extent that it suggests there is a causal connection between Victoza® and pancreatic cancer.

Subject to and without waiving or otherwise limiting the foregoing General and Specific objections, NNI refers Plaintiffs to its production of Organizational Charts bearing the Bates-prefix “NNI-OrgCharts.”

PRECLINICAL, NONCLINICAL AND ANIMAL STUDIES REQUEST REQUEST NO. 5:

A complete list of all VICTOZA preclinical, nonclinical and/or animal studies performed, completed, designed, planned and/or contemplated, identifying them by name, number or any other designation YOU use to identify them.

RESPONSE TO REQUEST NO. 5:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Request as vague and ambiguous as it fails to define key terms, including “planned” and “contemplated.” NNI further objects to this Request to the extent it requests information about Victoza® preclinical, nonclinical, and/or animal studies that have not been performed, completed, or designed by NNI.

Subject to and without waiving the foregoing General and Specific objections, NNI refers Plaintiffs to NNI’s production of its Nonclinical Study Chart and its supplements, reflecting the Bates prefix “NNI-StudyCharts,” which identify and describe preclinical, nonclinical, and/or animal studies conducted by Novo Nordisk on Victoza® that have been identified after reasonable inquiry.

1 **REQUEST NO. 6:**

2 For each VICTOZA preclinical, nonclinical and/or animal study performed,
3 completed, designed, planned and/or contemplated, produce the following:

- 4 a. The protocols; data; researcher and/or laboratory technician notebooks,
5 notes, logs, bench notes, books, computer files and emails; results; reports; and
6 pancreatic specimens (e.g. histology slides, tissue samples, etc.) for that study;
7 b. The database(s) where the above information can be located; and
8 c. If an independent investigator, contract research organization, or other
9 third party was involved in the study, produce all documents relating to the work
10 performed, including but not limited to contracts and communications between
11 YOU and said independent investigator, contract research organization, or other
12 third party.

13 **RESPONSE TO REQUEST NO. 6:**

14 NNI incorporates, as if fully set forth herein, the General Objections by
15 reference. NNI further objects to this Request as vague and ambiguous as it fails
16 to define key terms, including “planned” and “contemplated.” NNI further objects
17 to this Request to the extent it requests information about Victoza® preclinical,
18 nonclinical, and/or animal studies that have not been performed, completed, or
19 designed by Novo Nordisk. NNI further objects to this Request to the extent it
20 seeks the production of databases because NNI cannot produce “databases,” but
21 only the data and information within them. NNI further objects to this Request to
22 the extent it seeks information about NNI’s relationship with various third parties,
23 including contracts, which are outside the scope of general causation discovery
24 pursuant to this Court’s February 18 Order, which requires Plaintiffs to “narrow all
25 discovery related requests to issues involving general causation.”

26 Subject to and without waiving or otherwise limiting the foregoing General
27 and Specific objections, NNI refers Plaintiffs to NNI’s production of its
28 Nonclinical Study Chart and supplements, as described in NNI’s response to

1 Request No. 5. NNI also produced, and referenced by Bates-number, the
2 corresponding final report and protocol, where available, for each study identified
3 in the study chart. NNI will supplement its production, in accordance with the
4 deadlines ordered by the Court, with any outstanding final study reports and study
5 protocols maintained in the normal and ordinary course of business that correspond
6 to the studies listed on NNI's Nonclinical Study Chart.

7 NNI further states that laboratory notebooks and raw data, including, but not
8 limited to, notes, logs, bench notes, books, computer files, results, and pancreatic
9 specimens (e.g., histology slides, tissue samples, etc.) for completed and ongoing
10 preclinical, nonclinical, and/or animal studies conducted by Novo Nordisk on
11 Victoza® are maintained in accordance with regulatory standards by the Contract
12 Research Organization ("CRO") that performed the study. The identity of the CRO
13 can be found in the study report corresponding to each study. NNI will meet and
14 confer about providing inspection of these materials and data, if needed, at the
15 request of Plaintiffs.

16 **REQUEST NO. 7:**

17 The standard operating procedures and/or policy and procedures manuals for
18 VICTOZA preclinical, nonclinical and animal studies.

19 **RESPONSE TO REQUEST NO. 7:**

20 NNI incorporates, as if fully set forth herein, the General Objections by
21 reference. NNI further objects to this Request as overly broad and unduly
22 burdensome. NNI further objects to this Request to the extent it suggests that
23 there are standard operating procedures ("SOPs") and/or policy and procedures
24 manuals specific to Victoza® preclinical, nonclinical, and animal studies.

25 Subject to and without waiving or otherwise limiting the foregoing General
26 and Specific objections, NNI states that responsive documents may be found within
27 NNI's SOP production, reflecting the Bates prefix "NNI-SOP." As part of that

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1 production, NNI produced an index of Nonclinical SOPs and produced the SOPs
2 from that index as requested by Plaintiffs.

3 **REQUEST NO. 8:**

4 Every DOCUMENT that addresses the significance of any preclinical,
5 nonclinical and/or animal study in relation to whether VICTOZA CAUSES and/or
6 is capable of CAUSING pancreatic cancer.

7 **RESPONSE TO REQUEST NO. 8:**

8 NNI incorporates, as if fully set forth herein, the General Objections by
9 reference. NNI further objects to this Request as overly broad and unduly
10 burdensome to the extent it seeks “every” document. NNI further objects to this
11 Request as vague and ambiguous because it fails to define key terms, including
12 “significance.” NNI further objects to this Request to the extent that it suggests
13 there is a causal connection between Victoza® and pancreatic cancer. NNI
14 further objects to this Request to the extent it seeks documents related to
15 preclinical, nonclinical, and/or animal studies not conducted by Novo Nordisk on
16 Victoza®. NNI further objects to this Request to the extent it seeks documents
17 not maintained by NNI in the regular and ordinary course of business. NNI
18 further objects to this Request to the extent it seeks documents regarding foreign
19 regulatory activities.

20 Subject to and without waiving or otherwise limiting the foregoing General
21 and Specific Objections, NNI states that responsive information can be found, to
22 the extent it exists, in submissions to the FDA which are located within NNI’s
23 IND and NDA files for Victoza®, as identified in NNI’s response to Request No. 2.
24 NNI further states that responsive non-privileged documents can be found, to the
25 extent they exist, in custodial files for key custodians, including, but not limited to,
26 Lotte Knudsen, Jason Brett, and Alan Moses.

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1 **REQUEST NO. 9:**

2 The memoranda, reports and other similar DOCUMENTS that describe the
3 nature and intended purpose of any preclinical, nonclinical and/or animal studies
4 involving VICTOZA that are not yet started or completed and, to the extent such
5 DOCUMENTS exist, the protocols; data; researcher and/or laboratory technician
6 notebooks, notes, logs, bench notes, books, computer files and emails; results;
7 reports; and pancreatic specimens (e.g. histology slides, tissue samples, etc.) for
8 each such preclinical, nonclinical and/or animal study.

9 **RESPONSE TO REQUEST NO. 9:**

10 NNI incorporates, as if fully set forth herein, the General Objections by
11 reference. NNI further objects to this Request as vague and ambiguous because it
12 fails to define key terms, including “similar” and “not yet started.” NNI further
13 objects to this Request to the extent it seeks documents related to preclinical,
14 nonclinical, and/or animal studies not currently being planned and/or conducted
15 by Novo Nordisk on Victoza®. NNI further objects to this Request to the extent
16 it seeks documents not maintained by NNI in the regular and ordinary course of
17 business. NNI further objects to this Request to the extent it seeks documents
18 regarding foreign regulatory activities.

19 Subject to and without waiving or otherwise limiting the foregoing General
20 and Specific objections, NNI refers Plaintiffs to NNI’s production of its
21 Nonclinical Study Chart and supplements, as described in NNI’s responses to
22 Request Nos. 5 and 6, which includes information on approved, but not yet
23 started, preclinical, nonclinical, and/or animal studies for Victoza® to the extent
24 they exist.

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HUMAN STUDIES

REQUEST NO. 10:

A complete list of all VICTOZA human studies performed, completed, designed, planned and/or contemplated, identifying them by name, number or any other designation YOU use to identify them.

RESPONSE TO REQUEST NO. 10:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Request as vague and ambiguous as it fails to define key terms, including “planned” and “contemplated.” NNI further objects to this Request to the extent it requests information about Victoza® human studies that have not been performed, completed, or designed by NNI.

Subject to and without waiving or otherwise limiting the foregoing General and Specific objections, NNI refers Plaintiffs to NNI’s production of its Clinical Study chart and supplements, reflecting Bates prefix “NNI-StudyCharts,” which identify and describe human studies conducted by Novo Nordisk on Victoza® identified after reasonable inquiry.

REQUEST NO. 11:

For each VICTOZA human study performed, completed, designed, planned and/or contemplated, produce the following:

- a. The protocols; data; researcher and/or laboratory technician notebooks, notes, logs, bench notes, books, computer files and emails; results; reports; and pancreatic specimens (e.g. histology slides, tissue samples, etc.) for that study;
- b. The database(s) where the above information can be located;
- c. All documentation and/or communication regarding sponsorship of the study; and
- d. If an independent investigator, contract research organization, or other third party was involved in the study, produce all documents relating to the work performed, including but not limited to contracts and communications between

1 YOU and said independent investigator, contract research organization, or other
2 third party.

3 **RESPONSE TO REQUEST NO. 11:**

4 NNI incorporates, as if fully set forth herein, the General Objections by
5 reference. NNI further objects to this Request as vague and ambiguous as it fails
6 to define key terms, including “planned,” “contemplated,” and “database.” NNI
7 further objects to this Request to the extent it requests information about
8 Victoza® human studies that have not been conducted or are not being conducted
9 by Novo Nordisk. NNI further objects to this Request to the extent it seeks the
10 production of databases because NNI cannot produce “databases,” but only the
11 data and information within them. NNI further objects to this Request to the
12 extent it seeks information, including information about NNI’s relationships or
13 contracts with various third parties, that is outside the scope of general causation
14 discovery and inapplicable discovery at this time pursuant to this Court’s February
15 18 Order, which requires Plaintiffs to “narrow all discovery related requests to
16 issues involving general causation.”

17 Subject to and without waiving or otherwise limiting the foregoing General
18 and Specific objections, NNI refers Plaintiffs to NNI’s production of its Clinical
19 Study Chart and supplements, as described in NNI’s response to Request No. 10.
20 NNI also produced, and referenced by Bates-number, the corresponding final
21 report, protocol, and dataset, where available, for each study identified in the
22 study chart. NNI will supplement its production, in accordance with the deadlines
23 ordered by the Court, with any outstanding final study reports, protocols, and
24 datasets maintained in the normal and ordinary course of business that correspond
25 to the studies listed on NNI’s Clinical Study Chart.

26 NNI further states that patient level data for Victoza® human studies
27 conducted by Novo are maintained in accordance with regulatory standards in the
28 Trial Master File. NNI objects to producing its Trial Master File for every human

1 study on Victoza® because the significant burden imposed on producing the
2 information would far outweigh the information's limited relevance. NNI will meet
3 and confer with Plaintiffs about making this information available, if needed, for
4 specific studies upon request.

5 **REQUEST NO. 12:**

6 The standard operating procedures and/or policy and procedures manuals for
7 VICTOZA human studies.

8 **RESPONSE TO REQUEST NO. 12:**

9 NNI incorporates, as if fully set forth herein, the General Objections by
10 reference. NNI further objects to this Request to the extent it suggests that there
11 are standard operating procedures ("SOPs") and/or policy and procedures
12 manuals specific to Victoza®. NNI further objects to this Request as overly
13 broad and unduly burdensome.

14 Subject to and without waiving or otherwise limiting the foregoing General
15 and Specific objections, NNI states that responsive documents may be found within
16 NNI's SOP production, reflecting the Bates prefix "NNI-SOP." As part of that
17 production, NNI produced an index of CMR (Clinical, Medical, Regulatory) SOPs
18 and asked that Plaintiffs request the specific SOPs they would like produced.
19 Additionally, NNI's SOP production includes the training profile index for Kathryn
20 Owen, and NNI produced specific SOPs identified in that index as requested by
21 Plaintiffs.

22 **REQUEST NO. 13:**

23 Every DOCUMENT that records, analyzes or discusses information about
24 each person YOU are aware of who was a participant in a VICTOZA human study
25 and was diagnosed with pancreatitis and/or pancreatic cancer either while still
26 participating in the study or after withdrawing or otherwise being removed from the
27 study.

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1 **RESPONSE TO REQUEST NO. 13:**

2 NNI incorporates, as if fully set forth herein, the General Objections by
3 reference. NNI further objects to this Request as vague and ambiguous as it fails
4 to define key terms, including “records,” “analyzes,” or “discusses.” NNI further
5 objects to producing “every” document on the requested topic as it is unduly
6 burdensome. NNI further objects to this Request to the extent it requires NNI
7 disclose the identity of any individuals not named as Plaintiffs in this litigation who
8 allegedly experienced or reported a diagnosis of pancreatitis and/or pancreatic
9 cancer as such disclosure would violate the patients’ or reporters’ right to
10 confidentiality under federal law.

11 Subject to and without waiving or otherwise limiting the foregoing General
12 and Specific objections, NNI refers Plaintiffs to NNI’s adverse event production,
13 reflecting the Bates-prefix “NNI-AER,” which includes adverse event case reports
14 run from NNI’s Argus database for global Victoza® adverse events of pancreatic
15 cancer and pancreatitis through February 28, 2014 and a corresponding adverse
16 event spreadsheet.

17 **REQUEST NO. 14:**

18 Every DOCUMENT that addresses the significance of any human study in
19 relation to whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic
20 cancer.

21 **RESPONSE TO REQUEST NO. 14:**

22 NNI incorporates, as if fully set forth herein, the General Objections by
23 reference. NNI further objects to producing “every” document on the requested
24 topic as it is unduly burdensome. NNI further objects to this Request to the extent
25 that it suggests there is a causal connection between Victoza® and pancreatic
26 cancer. NNI further objects to this Request as vague and ambiguous, as it fails to
27 define key terms, including “significance.”

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1 Subject to and without waiving or otherwise limiting the foregoing General
2 and Specific objections, NNI refers Plaintiffs to NNI's Clinical Study Chart and
3 supplements; the corresponding study reports, protocols, and datasets, where
4 available, identified on the study charts; the IND and NDA production; and the
5 production of key custodial files, including, but not limited to, Alan Moses, Jason
6 Brett, Lotte Knudsen, Kathryn Owen, and Yizhen Xu.

7 **REQUEST NO. 15:**

8 The memoranda, reports and other similar DOCUMENTS that describe the
9 nature and intended purpose of any human studies involving VICTOZA that are not
10 yet started or completed and, to the extent such DOCUMENTS exist, the study
11 protocols; data; researcher and/or laboratory technician notebooks, notes, logs,
12 bench notes, books, computer files and emails; results; reports; and pancreatic
13 specimens (e.g. histology slides, tissue samples, etc.) for each such human study.

14 **RESPONSE TO REQUEST NO. 15:**

15 NNI incorporates, as if fully set forth herein, the General Objections by
16 reference. NNI further objects to this Request as vague and ambiguous, as it fails to
17 define key terms, including "not yet started." NNI further objects to this Request
18 to the extent it seeks documents related to human studies for Victoza® that are
19 not being or will not be conducted by Novo Nordisk, if at all.

20 Subject to and without waiving or otherwise limiting the foregoing General
21 and Specific objections, NNI refers Plaintiffs to NNI's production of its Clinical
22 Study Chart and supplements, as described in NNI's responses to Request Nos. 10
23 and 11, which includes information on approved, but not yet started, human studies
24 for Victoza® to the extent they exist.

25 **OBSERVATIONAL STUDIES**

26 **REQUEST NO. 16:**

27 A complete list of all VICTOZA observational studies (including, without
28 limitation, claims database studies, cohort studies and other epidemiological

1 studies) performed, completed, designed, planned and/or contemplated, identifying
2 them by name, number or any other designation YOU use to identify them.

3 **RESPONSE TO REQUEST NO. 16:**

4 NNI incorporates, as if fully set forth herein, the General Objections by
5 reference. NNI further objects to this Request as vague and ambiguous as it fails
6 to define key terms, including “planned” and “contemplated.” NNI further
7 objects to this Request to the extent it requests information about Victoza®
8 observational studies that have not been performed, completed, or designed by
9 NNI.

10 Subject to and without waiving or otherwise limiting the foregoing General
11 and Specific objections, NNI refers Plaintiffs to NNI’s production of its Clinical
12 Study chart and supplements, reflecting the Bates prefix “NNI-StudyCharts,”
13 which identify and describe observational studies conducted by Novo Nordisk on
14 Victoza® identified after reasonable inquiry.

15 **REQUEST NO. 17:**

16 For each VICTOZA observational study (including, without limitation,
17 claims database studies, cohort studies and other epidemiological studies)
18 performed, completed, designed, planned and/or contemplated, produce the
19 following:

- 20 a. The protocols; data; researcher and/or laboratory technician notebooks,
21 notes, logs, bench notes, books, computer files and emails; results; and reports for
22 that study;
- 23 b. The database(s) where the above information can be located; and
- 24 c. If an independent investigator, contract research organization, or other
25 third party was involved in the study, produce all documents relating to the work
26 performed, including but not limited to contracts and communications between
27 YOU and said independent investigator, contract research organization, or other
28 third party.

1 **RESPONSE TO REQUEST NO. 17:**

2 NNI incorporates, as if fully set forth herein, the General Objections by
3 reference. NNI further objects to this Request as vague and ambiguous as it fails to
4 define key terms, including “planned,” “contemplated,” and “database.” NNI
5 further objects to this Request to the extent it requests information about Victoza®
6 observational studies that have not been conducted or are not being conducted by
7 Novo Nordisk. NNI further objects to this Request to the extent it seeks the
8 production of databases because NNI cannot produce “databases,” but only the data
9 and information within them. NNI further objects to this Request to the extent it
10 seeks information, including information about NNI’s relationships or contracts
11 with various third parties, that is outside the scope of general causation discovery
12 and inapplicable discovery at this time pursuant to this Court’s February 18 Order,
13 which requires Plaintiffs to “narrow all discovery related requests to issues
14 involving general causation.”

15 Subject to and without waiving or otherwise limiting the foregoing General
16 and Specific objections, NNI refers Plaintiffs to NNI’s production of its Clinical
17 Study Chart and supplements, as described in NNI’s response to Request No. 16.
18 NNI also produced, and referenced by Bates-number, the corresponding final
19 report, protocol, and dataset, where available, for each study identified in the study
20 chart. NNI will supplement its production, in accordance with the deadlines
21 ordered by the Court, with any outstanding final study reports, protocols and
22 datasets maintained in the normal and ordinary course of business that correspond
23 to the studies listed on NNI’s Clinical Study Chart.

24 NNI further states that other data for Victoza® observational studies
25 conducted by Novo are maintained in accordance with regulatory standards in the
26 Trial Master File. NNI objects to producing its Trial Master File for every
27 observational study on Victoza® because the significant burden imposed on
28 producing the information would far outweigh the information’s limited relevance.

1 NNI will meet and confer with Plaintiffs about making this information available, if
2 needed, for specific studies upon request.

3 **REQUEST NO. 18:**

4 The standard operating procedures and/or policy and procedures manuals for
5 VICTOZA observational studies (including, without limitation, claims database
6 studies, cohort studies and other epidemiological studies).

7 **RESPONSE TO REQUEST NO. 18:**

8 NNI incorporates, as if fully set forth herein, the General Objections by
9 reference. NNI further objects to this Request to the extent it suggests that there
10 are standard operating procedures (“SOPs”) and/or policy and procedures
11 manuals specific to Victoza®. NNI further objects to this Request as overly
12 broad and unduly burdensome.

13 Subject to and without waiving or otherwise limiting the foregoing General
14 and Specific objections, NNI refers Plaintiffs to its response to Request No. 12.

15 **REQUEST NO. 19:**

16 Every DOCUMENT that addresses the significance of any observational
17 studies (including, without limitation, claims database studies, cohort studies and
18 other epidemiological studies) in relation to whether VICTOZA CAUSES and/or is
19 capable of CAUSING pancreatic cancer.

20 **RESPONSE TO REQUEST NO. 19:**

21 NNI incorporates, as if fully set forth herein, the General Objections by
22 reference. NNI further objects to producing “every” document on the requested
23 topic as it is unduly burdensome. NNI further objects to this Request to the extent
24 that it suggests there is a causal connection between Victoza® and pancreatic
25 cancer. NNI further objects to this Request as vague and ambiguous, as it fails to
26 define key terms, including “significance.”

27 Subject to and without waiving or otherwise limiting the foregoing General
28 and Specific objections, NNI refers Plaintiffs to NNI’s Clinical Study Chart and

1 supplements; the corresponding study reports, protocols, and datasets, where
2 available, identified on the study charts; the IND and NDA production; and the
3 production of key custodial files, including, but not limited to, Alan Moses, Jason
4 Brett, Lotte Knudsen, Kathryn Owen, and Yizhen Xu.

5 **REQUEST NO. 20:**

6 The memoranda, reports and other similar DOCUMENTS that describe the
7 nature and intended purpose of any observational studies (including, without
8 limitation, claims database studies, cohort studies and other epidemiological
9 studies) involving VICTOZA that are not yet started or completed and, to the extent
10 such DOCUMENTS exist, the study protocols; data; researcher and/or laboratory
11 technician notebooks, notes, logs, bench notes, books, computer files and emails;
12 results; and reports for each such study.

13 **RESPONSE TO REQUEST NO. 20:**

14 NNI incorporates, as if fully set forth herein, the General Objections by
15 reference. NNI further objects to this Request as vague and ambiguous, as it fails to
16 define key terms, including “not yet started.” NNI further objects to this Request
17 to the extent it seeks documents related to observational studies for Victoza® that
18 are not being or will not be conducted by Novo Nordisk, if at all.

19 Subject to and without waiving or otherwise limiting the foregoing General
20 and Specific objections, NNI refers Plaintiffs to NNI’s production of its Clinical
21 Study Chart and supplements, as described in NNI’s responses to Request Nos. 10
22 and 11, which includes information on approved, but not yet started, observational
23 studies for Victoza® to the extent they exist.

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**STUDIES TO DETERMINE CAUSAL CONNECTION
WITH PANCREATIC CANCER**

REQUEST NO. 21:

The standard operating procedures and/or policy and procedures manuals for VICTOZA studies undertaken to determine, in whole or in part, whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer.

RESPONSE TO REQUEST NO. 21:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Request to the extent that it suggests there is a causal connection between Victoza® and pancreatic cancer. NNI further objects to this Request to the extent it suggests that there are SOPs and/or policy and procedures manuals specific to Victoza®.

Without waiving or otherwise limiting the foregoing General and Specific Objections, NNI states that responsive information, to the extent it exists, can be found within NNI's SOP production, reflecting the Bates-prefix "NNI-SOP."

REQUEST NO. 22:

The study protocols; data; researcher and/or laboratory technician notebooks, notes, logs, bench notes, books, computer files and emails; results; and reports that were provided to the FDA for each study, test, investigation, evaluation and/or assessment undertaken by YOU for the purpose of determining, in whole or in part, whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer.

RESPONSE TO REQUEST NO. 22:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Request to the extent that it suggests there is a causal connection between Victoza® and pancreatic cancer.

Subject to and without waiving or otherwise limiting the foregoing General and Specific objections, NNI refers Plaintiffs to NNI's Nonclinical and Clinical Study Charts and supplements which identify and describe the studies conducted

1 by Novo Nordisk on Victoza® that have been identified after reasonable inquiry.
2 NNI refers Plaintiffs to NNI's production of IND and NDA files for Victoza®, as
3 identified in NNI's response to Request No. 2, which include the studies submitted
4 to the FDA.

5 **REQUEST NO. 23:**

6 The study protocols; data; researcher and/or laboratory technician notebooks,
7 notes, logs, bench notes, books, computer files and emails; results; and reports that
8 were not provided to the FDA for each study, test, investigation, evaluation and/or
9 assessment undertaken by YOU for the purpose of determining, in whole or in part,
10 whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer.

11 **RESPONSE TO REQUEST NO. 23:**

12 NNI incorporates, as if fully set forth herein, the General Objections by
13 reference. NNI further objects to this Request to the extent that it suggests there
14 is a causal connection between Victoza® and pancreatic cancer.

15 Subject to and without waiving or otherwise limiting the foregoing General
16 and Specific objections, NNI refers Plaintiffs to NNI's Nonclinical and Clinical
17 Study Charts and supplements which identify and describe the studies conducted
18 by Novo Nordisk on Victoza® that have been identified after reasonable inquiry.
19 NNI refers Plaintiffs to NNI's production of IND and NDA files for Victoza®, as
20 identified in NNI's response to Request No. 2, which include the studies
21 submitted to the FDA. NNI further refers Plaintiffs to its responses to Request
22 Nos. 6 and 11.

23 **REQUEST NO. 24:**

24 The study protocols; data; researcher and/or laboratory technician notebooks,
25 notes, logs, bench notes, books, computer files and emails; results; and reports that
26 were provided to the EMA for each study, test, investigation, evaluation and/or
27 assessment undertaken by YOU for the purpose of determining, in whole or in part,
28 whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer.

1 **RESPONSE TO REQUEST NO. 24:**

2 NNI incorporates, as if fully set forth herein, the General Objections by
3 reference. NNI further objects to this Request to the extent that it suggests there
4 is a causal connection between Victoza® and pancreatic cancer. NNI further
5 objects to this Request to the extent it requests information on what was, or was
6 not, submitted to the EMA because it has no bearing on general causation issues
7 in this litigation. NNI further objects to this Request to the extent it seeks
8 information regarding NNI's regulatory submissions to the EMA that are
9 duplicative of information submitted to the FDA.

10 Subject to and without waiving or otherwise limiting the foregoing General
11 and Specific objections, NNI refers Plaintiffs to NNI's Nonclinical and Clinical
12 Study Charts and supplements which identify and describe the studies conducted
13 by Novo Nordisk on Victoza® that have been identified after reasonable inquiry.
14 NNI further refers Plaintiffs to its responses to Request Nos. 6 and 11. NNI
15 further states that documents submitted to the EMA can be found in the EMA
16 regulatory files, which will be produced in this litigation through February 28,
17 2014 in searchable format and Plaintiffs will be in the same position as NNI to
18 locate and identify any further responsive information within this category of
19 documents. Data sets from the EMA regulatory files will be made available upon
20 request to the extent that they have not already been produced from the FDA files
21 or otherwise made available to Plaintiffs.

22 NNI agrees to produce the EMA files for Victoza® only under the unique
23 and specific facts of this case, namely, that NNI relies upon the EMA's July 2013
24 Assessment and the FDA and EMA's February 2014 Assessment as it relates to
25 general causation. NNI maintains its position that regulatory filings with foreign
26 agencies are irrelevant to product liability actions in the United States and should
27 not generally be produced in these litigations.

28 /////

1 **REQUEST NO. 25:**

2 The study protocols; data; researcher and/or laboratory technician notebooks,
3 notes, logs, bench notes, books, computer files and emails; results; and reports that
4 were not provided to the EMA for each study, test, investigation, evaluation and/or
5 assessment undertaken by YOU for the purpose of determining, in whole or in part,
6 whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer.

7 **RESPONSE TO REQUEST NO. 25:**

8 NNI incorporates, as if fully set forth herein, the General Objections by
9 reference. NNI further objects to this Request to the extent that it suggests there
10 is a causal connection between Victoza® and pancreatic cancer. NNI further
11 objects to this Request to the extent it requests information on what was, or was
12 not, submitted to the EMA because what was submitted to the EMA has no
13 bearing on general causation issues in this litigation. NNI further objects to this
14 Request to the extent it seeks information regarding NNI's regulatory
15 submissions to the EMA that are duplicative of information submitted to the
16 FDA. NNI further objects to the extent this Request is duplicative of Request
17 No. 24.

18 Subject to and without waiving or otherwise limiting the foregoing General
19 and Specific objections, NNI refers Plaintiffs to its response to Request No. 24.

20 **REQUEST NO. 26:**

21 Every DOCUMENT that addresses the significance of any study, test,
22 investigation, evaluation and/or assessment undertaken by YOU for the purpose of
23 determining, in whole or in part, whether VICTOZA CAUSES and/or is capable of
24 CAUSING pancreatic cancer, in relation to whether VICTOZA CAUSES and/or is
25 capable of CAUSING pancreatic cancer.

26 **RESPONSE TO REQUEST NO. 26:**

27 NNI incorporates, as if fully set forth herein, the General Objections by
28 reference. NNI further objects to this Request as overly broad and unduly

1 burdensome to the extent it seeks “every document.” NNI further objects to this
2 Request to the extent that it suggests there is a causal connection between
3 Victoza® and pancreatic cancer. NNI further objects to this Request as vague
4 and ambiguous as it fails to define key terms, including “significance.” NNI
5 objects to the Request to the extent it seeks information protected by the attorney-
6 client privilege and/or work product doctrine.

7 Subject to and without waiving or otherwise limiting the foregoing General
8 and Specific objections, NNI refers Plaintiffs to NNI’s Clinical Study Chart and
9 supplements; the corresponding study reports, protocols and datasets, where
10 available, identified on the study charts; the IND and NDA production; and the
11 production of key custodial files, including, but not limited to, Alan Moses, Jason
12 Brett, Lotte Knudsen, Kathryn Owen, and Yizhen Xu.

13 **REQUEST NO. 27:**

14 The memoranda, reports and other similar DOCUMENTS that describe the
15 nature and intended purpose of any study, test, investigation, evaluation and/or
16 assessment undertaken by YOU for the purpose of determining, in whole or in part,
17 whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer,
18 that is not yet started or completed and, to the extent such DOCUMENTS exist, the
19 study protocols; data; researcher and/or laboratory technician notebooks, notes,
20 logs, bench notes, books, computer files and emails; results; and reports for each
21 such study, test, investigation, evaluation and/or assessment.

22 **RESPONSE TO REQUEST NO. 27:**

23 NNI incorporates, as if fully set forth herein, the General Objections by
24 reference. NNI further objects to this Request to the extent that it suggests there
25 is a causal connection between Victoza® and pancreatic cancer. NNI further
26 objects to this Request as vague and ambiguous, as it fails to define key terms,
27 including “not yet started.” NNI further objects to this Request as being duplicative
28 of Request Nos. 9, 15, and 20.

1 Subject to and without waiving or otherwise limiting the foregoing General
2 and Specific Objections, NNI refers Plaintiffs to its responses to Requests Nos. 9,
3 15, and 20.

4 **OTHER STUDIES**

5 **REQUEST NO. 28:**

6 The standard operating procedures and/or policy and procedures manuals for
7 all other studies YOU are aware of that bear, in whole or in part, on whether
8 VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer (whether
9 such study, test, investigation, evaluation and/or assessment involves VICTOZA,
10 another GLP 1 receptor or DPP 4 inhibitor, any other drug, or no drug).

11 **RESPONSE TO REQUEST NO. 28:**

12 NNI incorporates, as if fully set forth herein, the General Objections by
13 reference. NNI further objects to this Request to the extent that it suggests there
14 is a causal connection between Victoza® and pancreatic cancer. NNI further
15 objects to this Request as vague, ambiguous, overly broad, and unduly
16 burdensome as it fails to define key terms, including “aware of.” NNI further
17 objects to this Request to the extent it suggests that there are SOPs and/or policy
18 and procedures manuals specific to Victoza®. NNI further objects to this
19 Request as overly broad and unduly burdensome. NNI objects to the Request to
20 the extent it seeks information protected by the attorney-client privilege and/or
21 work product doctrine. NNI further objects to this Request to the extent it is
22 duplicative of Request Nos. 7, 12, 18, and 21.

23 Subject to and without waiving or otherwise limiting the foregoing General
24 and Specific Objections, NNI refers Plaintiffs to its responses to Request Nos. 7,
25 12, 18, and 21.

26 **REQUEST NO. 29:**

27 Every DOCUMENT that addresses the significance of any other study, test,
28 investigation, evaluation and/or assessment YOU are aware of that bears, in whole

1 or in part, on whether VICTOZA CAUSES and/or is capable of CAUSING
2 pancreatic cancer (whether such study, test, investigation, evaluation and/or
3 assessment involves VICTOZA, another GLP 1 receptor or DPP 4 inhibitor, any
4 other drug, or no drug), in relation to whether VICTOZA CAUSES pancreatic
5 cancer.

6 **RESPONSE TO REQUEST NO. 29:**

7 NNI incorporates as if fully set forth herein the General Objections by
8 Reference. NNI further objects to this Request as overly broad and unduly
9 burdensome to the extent it seeks “every” document on this topic. NNI further
10 objects to this Request to the extent that it suggests there is a causal connection
11 between Victoza® and pancreatic cancer. NNI further objects to the term “aware
12 of” as overly broad and unduly burdensome. NNI further objects to this Request
13 as vague and ambiguous as it fails to define key terms, including “significance.”
14 NNI further objects to the extent that this Request relates to or seeks information
15 regarding products other than Victoza®. NNI objects to the Request to the extent
16 it seeks information protected by the attorney-client privilege and/or work product
17 doctrine. NNI further objects to this response to the extent it is duplicative of
18 Request Nos. 8, 14, 19, and 26.

19 Subject to and without waiving or otherwise limiting the foregoing General
20 and Specific Objections, NNI refers to its responses to Request Nos. 8, 14, 19, and
21 26.

22 **REQUEST NO. 30:**

23 The memoranda, reports and other similar DOCUMENTS that describe the
24 nature and intended purpose of any other study, test, investigation, evaluation
25 and/or assessment YOU are aware of that bears, in whole or in part, on whether
26 VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer (whether
27 such study, test, investigation, evaluation and/or assessment involves VICTOZA,
28 another GLP 1 receptor or DPP 4 inhibitor, any other drug, or no drug) that is not

1 yet started or completed and, to the extent such DOCUMENTS exist, the study
2 protocols; data; researcher and/or laboratory technician notebooks, notes, logs,
3 bench notes, books, computer files and emails; results; reports; and pancreatic
4 specimens (e.g., histology slides, tissue samples, etc.) for each such other study,
5 test, investigation, evaluation and/or assessment.

6 **RESPONSE TO REQUEST NO. 30:**

7 NNI incorporates as if fully set forth herein the General Objections by
8 Reference. NNI further objects to the term “aware of” as overly broad and
9 unduly burdensome. NNI further objects to this Request as vague and ambiguous
10 as it fails to define key terms, including “not yet started.” NNI further objects to
11 this Request to the extent that it suggests there is a causal connection between
12 Victoza® and pancreatic cancer. NNI further objects to this Request to the extent
13 it seeks documents related to studies that have not been conducted and/or that are
14 not currently being conducted by Novo Nordisk on Victoza®. NNI further
15 objects to the extent that this Request relates to or seeks information regarding
16 products other than Victoza®. NNI further objects to this Request to the extent it
17 is duplicative of Request Nos. 9, 15, 20, and 27.

18 Subject to and without waiving or otherwise limiting the foregoing General
19 and Specific Objections, NNI refers Plaintiffs to its responses to Request Nos. 9,
20 15, 20, and 27.

21 **FDA AND EMA**

22 **REQUEST NO. 31:**

23 The study protocols; data; researcher and/or laboratory technician notebooks,
24 notes, logs, bench notes, books, computer files and emails; results; reports; and
25 pancreatic specimens (e.g., histology slides, tissue samples, etc.) that were provided
26 to the FDA for any other study, test, investigation, evaluation and/or assessment
27 YOU are aware of that bears, in whole or in part, on whether VICTOZA CAUSES
28 and/or is capable of CAUSING pancreatic cancer (whether such study, test,

1 investigation, evaluation and/or assessment involves VICTOZA, another GLP 1
2 receptor or DPP 4 inhibitor, any other drug, or no drug).

3 **RESPONSE TO REQUEST NO. 31:**

4 NNI incorporates, as if fully set forth herein, the General Objections by
5 reference. NNI further objects to this Request as vague and ambiguous, as it fails to
6 define key terms including “aware of.” NNI further objects to this Request to the
7 extent that it suggests there is a causal connection between Victoza® and
8 pancreatic cancer. NNI further objects to this Request to the extent it seeks
9 documents related to studies that have not been conducted and/or that are not
10 currently being conducted by Novo Nordisk on Victoza®. NNI further objects to
11 this Request as overly broad and unduly burdensome. NNI further objects to the
12 extent that this Request relates to or seeks information regarding products other
13 than Victoza®.

14 Subject to and without waiving or otherwise limiting the foregoing General
15 and Specific Objections, NNI states that its communications with and
16 submissions to the FDA regarding studies on the safety of Victoza® can be found
17 in NNI’s IND and NDA production, as identified in NNI’s response to Request
18 No. 2.

19 **REQUEST NO. 32:**

20 The study protocols; data; researcher and/or laboratory technician notebooks,
21 notes, logs, bench notes, books, computer files and emails; results; reports; and
22 pancreatic specimens (e.g., histology slides, tissue samples, etc.) that were not
23 provided to the FDA for any other study, test, investigation, evaluation and/or
24 assessment YOU are aware of that bears, in whole or in part, on whether VICTOZA
25 CAUSES and/or is capable of CAUSING pancreatic cancer (whether such study,
26 test, investigation, evaluation and/or assessment involves VICTOZA, another
27 GLP 1 receptor or DPP 4 inhibitor, any other drug, or no drug).

28 /////

1 **RESPONSE TO REQUEST NO. 32:**

2 NNI incorporates, as if fully set forth herein, the General Objections by
3 reference. NNI further objects to this Request as vague and ambiguous, as it fails to
4 define key terms including “aware of.” NNI further objects to this Request to the
5 extent that it suggests there is a causal connection between Victoza® and
6 pancreatic cancer. NNI further objects to this Request to the extent it seeks
7 documents related to studies that have not been conducted and/or that are not
8 currently being conducted by Novo Nordisk on Victoza®. NNI further objects to
9 this Request as overly broad and unduly burdensome to the extent it seeks
10 information from numerous sources that may be obtained from fewer sources.
11 NNI further objects to the extent that this Request relates to or seeks information
12 regarding products other than Victoza®. NNI objects to this Request to the extent
13 it is duplicative of Request No. 6, 11, and 23.

14 Subject to and without waiving or otherwise limiting the foregoing General
15 and Specific Objections, NNI refers Plaintiffs to NNI’s Nonclinical and Clinical
16 Study Charts and supplements which identify and describe the studies conducted
17 by Novo Nordisk on Victoza® that have been identified after reasonable inquiry.
18 NNI refers Plaintiffs to NNI’s production of IND and NDA files for Victoza®, as
19 identified in NNI’s response to Request No. 2 that include the studies submitted
20 to the FDA. NNI further refers Plaintiffs to its responses to Request Nos. 6, 11,
21 and 23.

22 **REQUEST NO. 33:**

23 The study protocols; data; researcher and/or laboratory technician notebooks,
24 notes, logs, bench notes, books, computer files and emails; results; reports; and
25 pancreatic specimens (e.g., histology slides, tissue samples, etc.) that were provided
26 to the EMA for any other study, test, investigation, evaluation and/or assessment
27 YOU are aware of that bears, in whole or in part, on whether VICTOZA CAUSES
28 and/or is capable of CAUSING pancreatic cancer (whether such study, test,

1 investigation, evaluation and/or assessment involves VICTOZA, another GLP 1
2 receptor or DPP 4 inhibitor, any other drug, or no drug).

3 **RESPONSE TO REQUEST NO. 33:**

4 NNI incorporates, as if fully set forth herein, the General Objections by
5 reference. NNI further objects to this Request as vague and ambiguous, as it fails
6 to define key terms including “aware of.” NNI further objects to this Request to
7 the extent that it suggests there is a causal connection between Victoza® and
8 pancreatic cancer. NNI further objects to this Request to the extent it seeks
9 documents related to studies that have not been conducted and/or that are not
10 currently being conducted by Novo Nordisk. NNI further objects to the extent
11 that this Request relates to or seeks information regarding products other than
12 Victoza®. NNI objects to this Request to the extent it is duplicative of Request
13 No. 6, 11, and 24.

14 Subject to and without waiving or otherwise limiting the foregoing General
15 and Specific objections, NNI refers Plaintiffs to NNI’s Nonclinical and Clinical
16 Study Charts and supplements which identify and describe the studies conducted
17 by Novo Nordisk on Victoza® that have been identified after reasonable inquiry.
18 NNI further refers Plaintiffs to its responses to Request Nos. 6, 11, and 24.

19 **REQUEST NO. 34:**

20 The study protocols; data; researcher and/or laboratory technician notebooks,
21 notes, logs, bench notes, books, computer files and emails; results; reports; and
22 pancreatic specimens (e.g., histology slides, tissue samples, etc.) that were not
23 provided to the EMA for any other study, test, investigation, evaluation and/or
24 assessment YOU are aware of that bears, in whole or in part, on whether VICTOZA
25 CAUSES and/or is capable of CAUSING pancreatic cancer (whether such study,
26 test, investigation, evaluation and/or assessment involves VICTOZA, another
27 GLP 1 receptor or DPP 4 inhibitor, any other drug, or no drug).

28 /////

1 **RESPONSE TO REQUEST NO. 34:**

2 NNI incorporates, as if fully set forth herein, the General Objections by
3 reference. NNI further objects to this Request as vague and ambiguous, as it fails
4 to define key terms including “aware of.” NNI further objects to this Request to
5 the extent that it suggests there is a causal connection between Victoza® and
6 pancreatic cancer. NNI further objects to this Request to the extent it seeks
7 documents related to studies that have not been conducted and/or that are not
8 currently being conducted by Novo Nordisk on Victoza®. NNI further objects to
9 the extent that this Request relates to or seeks information regarding products
10 other than Victoza®. NNI further objects to this Request to the extent it requests
11 information on what was, or was not, submitted to the EMA because it has no
12 bearing on general causation issues in this litigation. NNI further objects to this
13 Request to the extent it seeks information regarding NNI’s regulatory submissions
14 to the EMA that are duplicative of information submitted to the FDA. NNI further
15 objects to this Request to the extent it is duplicative of Request No. 33.

16 Subject to and without waiving or otherwise limiting the foregoing General
17 and Specific Objections, NNI refers Plaintiffs to its response to Request No. 33.

18 **REQUEST NO. 35:**

19 All emails, letters, reports, memoranda and other written communications
20 YOU have sent to or received from any governmental agency (including, without
21 limitation, the FDA and EMA) or any other entity or person regarding whether
22 VICTOZA or any other GLP 1 agonist or DPP 4 inhibitor CAUSES and/or is
23 capable of CAUSING pancreatitis and/or pancreatic cancer.

24 **RESPONSE TO REQUEST NO. 35:**

25 NNI incorporates the General Objections by reference as if fully set forth
26 herein. NNI objects to this Request as overly broad and unduly burdensome to the
27 extent it seeks “all” emails, letters, reports, memoranda, and other written
28 communications from “any” governmental agency, entity, or person. NNI further

1 objects to the extent that this Request relates to or seeks information regarding
2 products other than Victoza®. NNI further objects to this Request to the extent it
3 seeks documents regarding foreign regulatory activities. NNI objects to the
4 Request to the extent it seeks information protected by the attorney-client
5 privilege and/or work product doctrine. NNI further objects to this Request to the
6 extent it is duplicative of Request Nos. 2, 3, 22, 24, 31, and 33.

7 Subject to and without waiving or otherwise limiting the foregoing General
8 and Specific Objections, NNI refers Plaintiffs to its responses to Request Nos. 2, 3,
9 22, 24, 31, and 33.

10 **REQUEST NO. 36:**

11 If any of YOUR employees, officers, directors, agents, contractors, key
12 opinion leaders, members of speakers' bureaus, advisory board members, or
13 scientific advisors corresponded with or supplied information or data to the
14 European Medicines Agency (EMA) about or in connection with any assessments
15 of whether VICTOZA or any other GLP 1 agonist or DPP 4 inhibitor CAUSES
16 and/or is capable of CAUSING pancreatic cancer (including, without limitation, as
17 reflected in the EMA's 2013 "Assessment report for GLP 1 based therapies" and its
18 2014 "Pancreatic Safety of Incretin Based Drugs FDA and EMA Assessment"),
19 produce the correspondence, information or data, and any correspondence or other
20 DOCUMENTS YOU received from the EMA in response.

21 **RESPONSE TO REQUEST NO. 36:**

22 NNI incorporates, as if fully set forth herein, the General Objections by
23 reference. NNI further objects to this Request as vague and ambiguous as it fails to
24 define certain terms and phrases, including "key opinion leader," "member of
25 speaker bureau," "advisory board member," and "scientific advisor," and
26 "corresponded with or supplied information or data." NNI further objects to this
27 Request to the extent it seeks information concerning non-NNI personnel. NNI
28 further objects to this Request to the extent it seeks information regarding products

1 other than Victoza®. NNI further objects to this Request to the extent it requests
2 information on what was, or was not, submitted to the EMA because it has no
3 bearing on general causation issues in this litigation. NNI further objects to this
4 Request to the extent it seeks information regarding NNI's regulatory submissions
5 to the EMA that are duplicative of information submitted to the FDA.

6 Subject to or without waiving or otherwise limiting the foregoing General
7 and Specific objections, NNI refers Plaintiffs to NNI's EMA regulatory files,
8 which will be produced in this litigation through February 28, 2104. Data sets
9 from the EMA regulatory files will be made available upon request to the extent
10 that they have not already been produced from the FDA files or otherwise made
11 available to Plaintiffs. NNI further refers Plaintiffs to the custodial file for Lotte
12 Knudsen.

13 NNI agrees to produce the EMA files for Victoza® only under the unique
14 and specific facts of this case, namely, that NNI relies upon the EMA's July 2013
15 Assessment and the FDA and EMA's February 2014 Assessment as it relates to
16 general causation. NNI maintains its position that regulatory filings with foreign
17 agencies are irrelevant to product liability actions in the United States and should
18 not generally be produced in these litigations.

19 **REQUEST NO. 37:**

20 If any of YOUR employees, officers, directors, agents, contractors, key
21 opinion leaders, members of speakers' bureaus, advisory board members, or
22 scientific advisors corresponded with or supplied information or data to the FDA
23 about or in connection with any assessments of whether VICTOZA or any other
24 GLP 1 agonist or DPP 4 inhibitor CAUSES and/or is capable of CAUSING
25 pancreatic cancer (including, without limitation, as reflected in the FDA's 2014
26 "Pancreatic Safety of Incretin Based Drugs FDA and EMA Assessment"), produce
27 the correspondence, information or data, and any correspondence or other
28 DOCUMENTS YOU received from the FDA in response.

1 **RESPONSE TO REQUEST NO. 37:**

2 NNI incorporates, as if fully set forth herein, the General Objections by
3 reference. NNI further objects to this Request as vague and ambiguous as it fails to
4 define certain terms and phrases, including “key opinion leader,” “member of
5 speaker bureau,” “advisory board member,” and “scientific advisor,” and
6 “corresponded with or supplied information or data.” NNI further objects to this
7 Request to the extent it seeks information concerning non-NNI personnel. NNI
8 further objects to this Request to the extent it seeks information regarding products
9 other than Victoza®.

10 Subject to and without waiving or otherwise limiting the foregoing General
11 and Specific Objections, NNI states that its communications with and submissions
12 to the FDA regarding studies on the safety of Victoza® can be found in NNI’s IND
13 and NDA production, as identified in NNI’s response to Request No. 2. NNI
14 further refers Plaintiffs to the custodial file for Michelle Thompson.

15 **ADVERSE EVENTS**

16 **REQUEST NO. 38:**

17 The standard operating procedures and/or policy and procedures manuals for
18 the handling of pancreatitis and pancreatic cancer ADVERSE EVENTS and
19 REPORTABLE EVENTS pertaining to VICTOZA.

20 **RESPONSE TO REQUEST NO. 38:**

21 NNI incorporates, as if fully set forth herein, the General Objections by
22 reference. NNI objects to this Request to the extent it suggests that there are
23 SOPs and/or policy and procedures manuals specific to Victoza® adverse events.
24 NNI further objects to this Request as overly broad and unduly burdensome.

25 Subject to and without waiving or otherwise limiting the foregoing General
26 and Specific objections, NNI states that responsive documents may be found within
27 NNI’s SOP production, reflecting the Bates prefix “NNI-SOP.” As part of that
28 production and in addition to the SOPs produced relevant to adverse events, NNI

1 also produced an index of SOPs included in the training profile for Michael Sacco
2 and asked that Plaintiffs request the specific SOPs they would like produced.

3 **REQUEST NO. 39:**

4 Produce in electronic format complete copies of all databases used to track,
5 trend, or record information regarding pancreatitis and pancreatic cancer
6 ADVERSE EVENTS that YOU associated with VICTOZA. To the extent that
7 YOUR databases incorporate the following information for pancreatitis and
8 pancreatic cancer ADVERSE EVENTS for VICTOZA, this Request includes:

9 a. All DOCUMENTS and information in YOUR possession regarding
10 each ADVERSE EVENT;

11 b. Whether the ADVERSE EVENT was in the form of a MedWatch
12 Report, communication from a medical provider or consumer, an ADVERSE
13 EVENT REPORT (“AER”) or some other form;

14 c. All attempts YOU made to communicate with anyone to gather further
15 information regarding each ADVERSE EVENT;

16 d. All communications YOU made or received, including the substance
17 of the communications, the identities of any persons YOU communicated with
18 internally, and the identities of any persons YOU communicated with externally
19 regarding each ADVERSE EVENT;

20 e. The nature and results of any investigations YOU conducted to
21 determine the CAUSE of each ADVERSE EVENT, and/or the basis of any
22 decisions not to investigate;

23 f. Any experts and/or consultants whom YOU contacted regarding any
24 ADVERSE EVENT;

25 g. YOUR deliberations and decision making processes used to determine
26 whether each ADVERSE EVENT was or was not a REPORTABLE EVENT;

27 h. Any action YOU took as a result of each ADVERSE EVENT;

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- 1 i. YOUR analysis and conclusions as to the nature, severity and
2 frequency of each ADVERSE EVENT;
- 3 j. All ADVERSE EVENT report forms, including supplemental reports
4 and related information, that were submitted to the FDA for each ADVERSE
5 EVENT;
- 6 k. The current status or final disposition of each ADVERSE EVENT; and
- 7 l. Any reporting rates analysis and/or trending analysis done regarding
8 each ADVERSE EVENT.

9 To the extent that YOUR databases do not incorporate some or all of the
10 information referenced above in subparts a 1, produce the equivalent information
11 by reference to the business records in which YOU store it.

12 **RESPONSE TO REQUEST NO. 39:**

13 NNI incorporates, as if fully set forth herein, the General Objections by
14 reference. NNI further objects to this Request to the extent it seeks production of
15 databases as NNI cannot produce “databases,” but only data and information
16 residing within them. NNI further objects to this Request as overly broad and
17 unduly burdensome. NNI further objects to this Request to the extent it requests
18 source files for adverse events, which are unduly burdensome and not relevant for
19 general causation purposes. NNI further objects to this Request to the extent it
20 requires NNI disclose the identity of any individuals not named as Plaintiffs in this
21 litigation who allegedly experienced or reported a diagnosis of pancreatitis and/or
22 pancreatic cancer as such disclosure would violate the patients’ or reporters’ right
23 to confidentiality under federal law.

24 Subject to and without waiving or otherwise limiting the foregoing General
25 and Specific Objections, NNI refers Plaintiffs to NNI’s adverse event production,
26 reflecting the Bates-prefix “NNI-AER,” which includes adverse event case reports
27 run from NNI’s Argus database for global Victoza® adverse events of pancreatic
28 cancer and pancreatitis through February 28, 2014 and a corresponding adverse

1 event spreadsheet. NNI further refers Plaintiffs to NNI's production of IND and
2 NDA files for Victoza®, as identified in NNI's response to Request No. 2. NNI
3 further refers Plaintiffs to the custodial file of Michael Sacco.

4 **REQUEST NO. 40:**

5 The complete file that YOU established and maintain in response to each
6 individual pancreatitis and pancreatic cancer ADVERSE EVENT for VICTOZA
7 (commonly known as "source files," ADVERSE EVENT report files, backup files,
8 or files containing source documentation related to ADVERSE EVENTS). This
9 request seeks the production of all DOCUMENTS and information contained or
10 discussed in the source files for each ADVERSE EVENT, which should contain
11 most or all of the DOCUMENTS and information described in the preceding
12 request in subparts a-1.

13 **RESPONSE TO REQUEST NO. 40:**

14 NNI incorporates, as if fully set forth herein, the General Objections by
15 reference. NNI further objects to this Request as overly broad and unduly
16 burdensome. NNI further objects to this Request to the extent it requests source
17 files for adverse events, which are unduly burdensome and not relevant for
18 general causation purposes. NNI further objects to this Request to the extent it
19 requires NNI disclose the identity of any individuals not named as Plaintiffs in this
20 litigation who allegedly experienced or reported a diagnosis of pancreatitis and/or
21 pancreatic cancer as such disclosure would violate the patients' or reporters' right
22 to confidentiality under federal law. NNI further objects to this Request as it seeks
23 information duplicative of that sought in Request No. 39.

24 Subject to and without waiving or otherwise limiting the foregoing General
25 and Specific Objections, NNI refers Plaintiffs to its response to Request No. 39.

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1 **REQUEST NO. 41:**

2 To the extent not already produced in response to the preceding requests,
3 produce all DOCUMENTS for each pancreatitis and pancreatic cancer

4 REPORTABLE EVENT for VICTOZA, including the following:

5 a. All DOCUMENTS and information in YOUR possession regarding
6 each REPORTABLE EVENT;

7 b. Whether the REPORTABLE EVENT was in the form of a MedWatch
8 Report, communication from a medical provider or consumer, an ADVERSE
9 EVENT REPORT (“AER”) or some other form;

10 c. All attempts YOU made to communicate with anyone to gather further
11 information regarding each REPORTABLE EVENT;

12 d. All communications YOU made or received, including the substance
13 of the communications, the identities of any persons YOU communicated with
14 internally, and the identities of any persons YOU communicated with externally
15 regarding each REPORTABLE EVENT;

16 e. The nature and results of any investigations YOU conducted to
17 determine the CAUSE of each REPORTABLE EVENT, and/or the basis of any
18 decisions not to investigate;

19 f. Any experts and/or consultants whom YOU contacted regarding any
20 REPORTABLE EVENT;

21 g. YOUR deliberations and decision making processes used to determine
22 whether each underlying ADVERSE EVENT was or was not a REPORTABLE
23 EVENT;

24 h. Any action YOU took as a result of each REPORTABLE EVENT;

25 i. YOUR analysis and conclusions as to the nature, severity and
26 frequency of each REPORTABLE EVENT;

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j. All REPORTABLE EVENT report forms, including supplemental reports and related information, that were submitted to the FDA for each REPORTABLE EVENT;

k. The current status or final disposition of each REPORTABLE EVENT; and

l. Any reporting rates analysis and/or trending analysis done regarding each REPORTABLE EVENT.

RESPONSE TO REQUEST NO. 41:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Request as overly broad and unduly burdensome. NNI further objects to this Request to the extent it requests source files for adverse events, which are unduly burdensome and not relevant for general causation purposes. NNI further objects to this Request to the extent it requires NNI disclose the identity of any individuals not named as Plaintiffs in this litigation who allegedly experienced or reported a diagnosis of pancreatitis and/or pancreatic cancer as such disclosure would violate the patients' or reporters' right to confidentiality under federal law. NNI further objects to this Request as it seeks information duplicative of that sought in Request No. 39.

Subject to and without waiving or otherwise limiting the foregoing General and Specific Objections, NNI refers Plaintiffs to its response to Request No. 39.

REQUEST NO. 42:

All DOCUMENTS that state or discuss any request by the FDA that YOU conduct post market surveillance of VICTOZA with respect to pancreatitis and pancreatic cancer. Include in your response any correspondence, plans, reports, or other DOCUMENTS submitted by YOU to the FDA in response.

RESPONSE TO REQUEST NO. 42:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Request as overly broad and unduly

1 burdensome to the extent it seeks “all” documents on this topic. NNI objects to the
2 Request to the extent it seeks information protected by the attorney-client
3 privilege and/or work product doctrine.

4 Subject to and without waiving or otherwise limiting the foregoing General
5 and Specific Objections, NNI refers Plaintiffs to NNI’s adverse event production,
6 reflecting the Bates-prefix “NNI-AER,” which includes adverse event case reports
7 run from NNI’s Argus database for global Victoza® adverse events of pancreatic
8 cancer and pancreatitis through February 28, 2014 and a corresponding adverse
9 event spreadsheet. NNI refers Plaintiffs to its IND and NDA productions as
10 identified in NNI’s response to request No. 2. NNI further refers Plaintiffs to the
11 custodial files of Michael Sacco and Michelle Thompson for responsive
12 information, to the extent it exists.

13 **REQUEST NO. 43:**

14 All charts, graphs, schematics, reports, memoranda and other similar
15 DOCUMENTS analyzing, summarizing and/or reporting on pancreatitis and/or
16 pancreatic cancer ADVERSE EVENTS for VICTOZA, including all such
17 DOCUMENTS that compare VICTOZA to any other therapeutic agent(s) for the
18 treatment of type 2 diabetes. To the extent that such DOCUMENTS were prepared
19 in color, they should also be produced in color.

20 **RESPONSE TO REQUEST NO. 43:**

21 NNI incorporates, as if fully set forth herein, the General Objections by
22 reference. NNI further objects to this Request as overly broad and unduly
23 burdensome to the extent it seeks “all” documents on this topic.

24 Subject to and without waiving or otherwise limiting the foregoing General
25 and Specific Objections, NNI states that responsive information may be found, to
26 the extent it exists, in NNI’s adverse event production, reflecting the Bates-prefix
27 “NNI-AER,” which includes adverse event case reports run from NNI’s Argus
28 database for global Victoza® adverse events of pancreatic cancer and pancreatitis

1 through February 28, 2014 and a corresponding adverse event spreadsheet; NNI's
2 IND and NDA productions; and the custodial files of key witnesses, including, but
3 not limited to, Michael Sacco, Alan Moses, Jason Brett, and Michelle Thompson.

4 **REQUEST NO. 44:**

5 All reports, memoranda and other DOCUMENTS that list and/or explain the
6 criteria YOU use to determine whether any particular pancreatitis and/or pancreatic
7 cancer ADVERSE EVENT is related to the patient's use of VICTOZA.

8 **RESPONSE TO REQUEST NO. 44:**

9 NNI incorporates, as if fully set forth herein, the General Objections by
10 reference. NNI further objects to this Request as overly broad and unduly
11 burdensome to the extent it seeks "all" documents on this topic. NNI further
12 objects to this Request to the extent that it suggests there is a causal connection
13 between Victoza® and pancreatic cancer.

14 Subject to and without waiving or otherwise limiting the foregoing General
15 and Specific objections, NNI states that responsive documents may be found within
16 NNI's SOP production, including but not limited to "Handling of Adverse Events
17 and Other Safety Information" and "Filing of Adverse Events and Other Safety
18 Information in Argus," reflecting the Bates-prefix "NNI-SOP." NNI further states
19 that responsive information may be found, to the extent it exists, within the
20 custodial files of key custodians, including, but not limited to, Michael Sacco, Alan
21 Moses, and Jason Brett.

22 **REQUEST NO. 45:**

23 All medical and scientific literature that YOUR company has identified that
24 relates to the association between VICTOZA or any other GLP 1 agonist or DPP 4
25 inhibitor and pancreatitis and/or pancreatic cancer.

26 **RESPONSE TO REQUEST NO. 45:**

27 NNI incorporates, as if fully set forth herein, the General Objections by
28 reference. NNI further objects to this Request as overly broad and unduly

1 burdensome to the extent it seeks “all” medical and scientific literature. NNI
2 further objects to the extent this Request calls for information either not within
3 NNI’s possession, custody, or control and/or information that is a matter of public
4 record or otherwise as accessible to Plaintiffs as to NNI. NNI further objects to the
5 extent that this Request relates to or seeks information regarding products other
6 than Victoza®.

7 Subject to and without waiving or otherwise limiting the foregoing General
8 and Specific Objections, NNI refers Plaintiffs to Appendix A to NNI’s
9 Interrogatory Objections and Responses which lists the medical literature regarding
10 Victoza® that is centrally stored in the ordinary course of business by NNI. NNI
11 states that Plaintiffs can publicly obtain this literature to the extent they wish to
12 review it. NNI further states that responsive information can be found, to the extent
13 it exists, in the custodial files for key custodians, including, but not limited to, Alan
14 Moses, Jason Brett, and Lotte Knudsen. NNI further refers Plaintiffs to its IND and
15 NDA productions, which include submissions of medical literature.

16 **REQUEST NO. 46:**

17 All reports, analyses, presentations, memoranda and other DOCUMENTS
18 YOU are aware of that address, in whole or in part, whether VICTOZA or any other
19 GLP 1 agonist or DPP 4 inhibitor CAUSES and/or is capable of CAUSING
20 pancreatitis and/or pancreatic cancer.

21 **RESPONSE TO REQUEST NO. 46:**

22 NNI incorporates, as if fully set forth herein, the General Objections by
23 reference. NNI further objects to this Request as overly broad and unduly
24 burdensome to the extent it seeks “all” reports, analyses, presentations, memoranda
25 and other documents that NNI is “aware of.” NNI further objects to this Request as
26 vague and ambiguous, as it fails to define key terms, including “address.” NNI
27 further objects to the extent this Request calls for information either not within
28 NNI’s possession, custody, or control and/or information that is a matter of public

1 record or otherwise as accessible to Plaintiffs as to NNI. NNI further objects to the
2 extent that this Request relates to or seeks information regarding products other
3 than Victoza®. NNI further objects to this Request to the extent that it suggests
4 there is a causal connection between Victoza® and pancreatic cancer.

5 Subject to and without waiving or otherwise limiting the foregoing General
6 and Specific Objections, NNI states that responsive information may be found, to
7 the extent it exists, in the custodial for key custodians, including, but not limited to,
8 Alan Moses, Jason Brett, and Lotte Knudsen.

9 **REQUEST NO. 47:**

10 To the extent not already produced in response to the preceding requests, all
11 published and unpublished medical and scientific literature, reports, analyses,
12 presentations, memoranda and other DOCUMENTS YOU are aware of that address
13 whether VICTOZA or any other GLP 1 agonist or DPP 4 inhibitor CAUSES the
14 proliferation of abnormal or dysfunctional beta cells; the proliferation of abnormal
15 or dysfunctional alpha cells; the expansion of pancreatic ductal glands in rats; the
16 formation of dysplastic lesions and chronic pancreatitis in mice; increases in the
17 weight and/or size of the exocrine pancreas; the inhibition of apoptosis of
18 pancreatic ductal cells; and the inhibition of apoptosis of pancreatic islet cells.

19 **RESPONSE TO REQUEST NO. 47:**

20 NNI incorporates, as if fully set forth herein, the General Objections by
21 reference. NNI further objects to this Request as overly broad and unduly
22 burdensome to the extent it seeks “all” published and unpublished medical and
23 scientific literature, reports, analyses, presentations, memoranda, and other
24 documents that NNI is “aware of.” NNI further objects to this Request as vague
25 and ambiguous, as it fails to define key terms, including “address” and “medical
26 and scientific literature.” NNI further objects to the extent this Request calls for
27 information either not within NNI’s possession, custody, or control and/or
28 information that is a matter of public record or otherwise as accessible to Plaintiffs

1 as to NNI. NNI further objects to the extent that this Request relates to or seeks
2 information regarding products other than Victoza®. NNI further objects to this
3 Request to the extent it is duplicative of Request Nos. 45 and 46.

4 Subject to and without waiving or otherwise limiting the foregoing General
5 and Specific Objections, NNI refers Plaintiffs to its responses to Request Nos. 45
6 and 46.

7 **REQUEST NO. 48:**

8 To the extent not already produced in response to the preceding requests, all
9 published and unpublished medical and scientific literature, reports, analyses,
10 presentations, memoranda and other DOCUMENTS YOU are aware of that address
11 the mechanism of action of VICTOZA or any other GLP 1 agonist or DPP 4
12 inhibitor.

13 **RESPONSE TO REQUEST NO. 48:**

14 NNI incorporates, as if fully set forth herein, the General Objections by
15 reference. NNI further objects to this Request as overly broad and unduly
16 burdensome to the extent it seeks “all” published and unpublished medical and
17 scientific literature, reports, analyses, presentations, memoranda, and other
18 documents that NNI is “aware of.” NNI further objects to this Request as vague
19 and ambiguous, as it fails to define key terms, including “address” and “medical
20 and scientific literature.” NNI further objects to the extent this Request calls for
21 information either not within NNI’s possession, custody, or control and/or
22 information that is a matter of public record or otherwise as accessible to Plaintiffs
23 as to NNI. NNI further objects to the extent that this Request relates to or seeks
24 information regarding products other than Victoza®.

25 Subject to and without waiving or otherwise limiting the foregoing General
26 and Specific Objections, NNI refers Plaintiffs to its responses to Request Nos. 45
27 and 46.

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1 **REQUEST NO. 49:**

2 To the extent not already produced in response to the preceding requests, all
3 published and unpublished medical and scientific literature, reports, analyses,
4 presentations, memoranda and other DOCUMENTS YOU are aware of that address
5 the effect that VICTOZA or any other GLP 1 agonist or DPP 4 inhibitor has on the
6 pancreas.

7 **RESPONSE TO REQUEST NO. 49:**

8 NNI incorporates, as if fully set forth herein, the General Objections by
9 reference. NNI further objects to this Request as overly broad and unduly
10 burdensome to the extent it seeks “all” published and unpublished medical and
11 scientific literature, reports, analyses, presentations, memoranda, and other
12 documents that NNI is “aware of.” NNI further objects to this Request as vague
13 and ambiguous, as it fails to define key terms, including “address” and “medical
14 and scientific literature.” NNI further objects to the extent this Request calls for
15 information either not within NNI’s possession, custody, or control and/or
16 information that is a matter of public record or otherwise as accessible to Plaintiffs
17 as to NNI. NNI further objects to the extent that this Request relates to or seeks
18 information regarding products other than Victoza®.

19 Subject to and without waiving or otherwise limiting the foregoing General
20 and Specific Objections, NNI refers Plaintiffs to its responses to Request Nos. 45
21 and 46.

22 **REQUEST NO. 50:**

23 All reports, memoranda and other DOCUMENTS that list and/or explain the
24 criteria YOU use to determine whether VICTOZA or any other GLP 1 agonist or
25 DPP 4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or
26 pancreatic cancer.

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1 **RESPONSE TO REQUEST NO. 50:**

2 NNI incorporates, as if fully set forth herein, the General Objections by
3 reference. NNI further objects to the extent that this Request relates to or seeks
4 information regarding products other than Victoza®. NNI further objects to this
5 Request to the extent that it suggests there is a causal connection between Victoza®
6 and pancreatic cancer.

7 Subject to and without waiving or otherwise limiting the foregoing General
8 and Specific Objections, NNI states that responsive documents can be found, to the
9 extent they exist, within the custodial files of key custodians, including, but not
10 limited to, Alan Moses, Michael Sacco, Jason Brett, Michelle Thompson, and Lotte
11 Knudsen.

12 **REQUEST NO. 51:**

13 All medical and/or scientific literature that YOU have reported to the FDA or
14 any other regulatory authorities that relates to the association between VICTOZA
15 and pancreatitis and/or pancreatic cancer, including, but not limited to, all PSURs,
16 PADERS/PAERS, and independent submissions.

17 **RESPONSE TO REQUEST NO. 51:**

18 NNI incorporates, as if fully set forth herein, the General Objections by
19 reference. NNI further objects to this Request as vague and ambiguous as it fails to
20 define key terms, including “medical and/or scientific literature.” NNI objects to
21 this Request to the extent it requests information concerning regulatory authorities
22 outside of the U.S. because they are not relevant to litigation in the U.S.

23 Subject to and without waiving or otherwise limiting the foregoing General
24 and Specific Objections, NNI refers Plaintiffs to NNI’s IND and NDA productions,
25 as identified in NNI’s response to Request No. 2. NNI further states that
26 documents submitted to the EMA can be found in the EMA regulatory files,
27 which will be produced in this litigation through February 28, 2014 in searchable

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1 format and Plaintiffs will be in the same position as NNI to locate and identify
2 any further responsive information within this category of documents.

3 NNI agrees to produce the EMA files for Victoza® only under the unique
4 and specific facts of this case, namely, that NNI relies upon the EMA's July 2013
5 Assessment and the FDA and EMA's February 2014 Assessment as it relates to
6 general causation. NNI maintains its position that regulatory filings with foreign
7 agencies are irrelevant to product liability actions in the United States and should
8 not generally be produced in these litigations.

9 **REQUEST NO. 52:**

10 To the extent not already produced in response to the preceding requests,
11 produce all communications, analyses, expert analyses, safety board analyses,
12 independent analyses, and/or meta analyses that pertain to, reference, or in any way
13 discuss any of the medical and scientific literature and/or the preclinical,
14 nonclinical, animal, human, observational and/or other studies referred to above
15 with respect to whether VICTOZA or any other GLP 1 agonist or DPP 4 inhibitor
16 CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic cancer.

17 **RESPONSE TO REQUEST NO. 52:**

18 NNI incorporates, as if fully set forth herein, the General Objections by
19 reference. NNI further objects to this Request as overly broad and unduly
20 burdensome to the extent it seeks "*all* communications, analyses, expert analyses,
21 safety board analyses, independent analyses, and/or meta-analyses that *pertain to,*
22 *reference, or in any way* discuss *any* of the medical and scientific literature
23 and/or the preclinical, nonclinical, animal human, observational or/other studies."
24 NNI further objects to the extent that this Request relates to or seeks information
25 regarding products other than Victoza®. NNI further objects to the extent this
26 Request calls for information either not within NNI's possession, custody, or
27 control and/or information that is a matter of public record or otherwise as
28 accessible to Plaintiffs as to NNI. NNI objects to the Request to the extent it seeks

1 information protected by the attorney-client privilege and/or work product
2 doctrine.

3 Subject to and without waiving or otherwise limiting the foregoing General
4 and Specific Objections, NNI states that responsive documents can be found, to the
5 extent they exist, within the custodial files of NNI's key custodians, Alan Moses,
6 Michael Sacco, Jason Brett, Michelle Thompson, Kathryn Owen, Yizhen Xu, and
7 Lotte Knudsen.

8 **COMMUNICATIONS REGARDING CAUSAL CONNECTION**
9 **WITH PANCREATIC CANCER**

10 **REQUEST NO. 53:**

11 All communications YOU have had with the author(s) of the medical and/or
12 scientific literature referenced above with respect to whether VICTOZA or any
13 other GLP 1 agonist or DPP 4 inhibitor CAUSES and/or is capable of CAUSING
14 pancreatic cancer.

15 **RESPONSE TO REQUEST NO. 53:**

16 NNI incorporates, as if fully set forth herein, the General Objections by
17 reference. NNI further objects to this Request as overly broad and unduly
18 burdensome to the extent it seeks "all communications" related to a voluminous
19 body of "medical and/or scientific literature" sought by Plaintiffs that is not
20 identified in this Request. NNI further objects to this Request as vague and
21 ambiguous as it fails to define key terms, including "medical and/or scientific
22 literature." NNI further objects to this Request to the extent that it suggests there is
23 a causal connection between Victoza® and pancreatic cancer.

24 Subject to and without waiving or otherwise limiting the foregoing General
25 and Specific Objections, NNI states that responsive documents can be found, to the
26 extent they exist, within the custodial files of NNI's key custodians, Alan Moses,
27 Michael Sacco, Jason Brett, Michelle Thompson, Kathryn Owen, Yizhen Xu, and
28 Lotte Knudsen.

1 **REQUEST NO. 54:**

2 All emails, letters, reports, memoranda and other written communications
3 YOU have had internally regarding whether VICTOZA or any other GLP 1 agonist
4 or DPP 4 inhibitor CAUSES and/or is capable of CAUSING pancreatic cancer.

5 **RESPONSE TO REQUEST NO. 54:**

6 NNI incorporates, as if fully set forth herein, the General Objections by
7 reference. NNI further objects to this Request as overly broad and unduly
8 burdensome to the extent it requests NNI produce “all” emails, reports, memoranda,
9 and other written communications. NNI further objects to the extent that this
10 Request relates to or seeks information regarding products other than Victoza®.
11 NNI further objects to this Request to the extent that it suggests there is a causal
12 connection between Victoza® and pancreatic cancer.

13 Subject to and without waiving or otherwise limiting the foregoing General
14 and Specific Objections, NNI states that responsive documents can be found, to the
15 extent they exist, within the custodial files of NNI’s key custodians, Alan Moses,
16 Michael Sacco, Jason Brett, Michelle Thompson, Kathryn Owen, Yizhen Xu, and
17 Lotte Knudsen.

18 **REQUEST NO. 55:**

19 If YOU have made and/or requested label changes in the United States or
20 elsewhere to add or strengthen warnings about the risks of pancreatitis and/or
21 pancreatic cancer associated with VICTOZA at any time since YOU began to
22 market VICTOZA, provide all DOCUMENTS, including emails, letters, reports,
23 memoranda and other written communications, that YOU have sent to or received
24 from the FDA and/or any applicable foreign country’s regulatory authority in
25 connection with each label change and/or request. This request to produce
26 includes, without limitation, any PAS or CBE submitted by YOU to the FDA, and
27 any response YOU have received from the FDA.

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1 **RESPONSE TO REQUEST NO. 55:**

2 NNI incorporates, as if fully set forth herein, the General Objections by
3 reference. NNI further objects to the extent this Request seeks information
4 regarding foreign regulatory activities.

5 Subject to and without waiving the foregoing General and Specific
6 Objections, NNI refers Plaintiffs to NNI's IND and NDA production, as identified
7 in NNI's response to Request No. 2. NNI further refers Plaintiffs to its production
8 of product labels and medication guides for Victoza® approved by the FDA
9 produced with Bates-prefix "NNI-label."

10 **REQUEST NO. 56:**

11 All emails, letters, reports, memoranda and other written communications to
12 or from any source discussing or referring to physician monitoring and/or testing
13 for pancreatitis and/or pancreatic cancer associated with the use of VICTOZA.

14 **RESPONSE TO REQUEST NO. 56:**

15 NNI incorporates, as if fully set forth herein, the General Objections by
16 reference. NNI further objects to this Request as overly broad and unduly
17 burdensome to the extent it seeks "all" emails, letters, reports, memoranda and
18 other communications "to or from any source." NNI objects to the Request to the
19 extent it seeks information protected by the attorney-client privilege and/or work
20 product doctrine. NNI further objects to this Request as vague and ambiguous
21 because the term "physician monitoring" is undefined and renders the Request
22 unintelligible.

23 **REQUEST NO. 57:**

24 The meeting minutes and any summaries of meeting minutes for each
25 internal meeting at which YOU discussed whether VICTOZA or any other GLP 1
26 agonist or DPP 4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis
27 and/or pancreatic cancer.

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1 **RESPONSE TO REQUEST NO. 57:**

2 NNI incorporates, as if fully set forth herein, the General Objections by
3 reference. NNI further objects to this Request to the extent that it relates to or
4 seeks information regarding products other than Victoza®. NNI further objects to
5 this Request to the extent that it suggests there is a causal connection between
6 Victoza® and pancreatic cancer. NNI further objects to this Request as overly
7 broad and unduly burdensome as it requests information for “each” internal meeting
8 on this topic. NNI further objects to this Request to the extent “internal meeting” is
9 not defined and is vague and ambiguous.

10 Subject to and without waiving or otherwise limiting the foregoing General
11 and Specific Objections, NNI states that responsive documents can be found, to the
12 extent they exist, within the custodial files of key custodians, Alan Moses, Michael
13 Sacco, Jason Brett, Michelle Thompson, Kathryn Owen, Yizhen Xu, and Lotte
14 Knudsen. NNI further states that to the extent it identifies meeting minutes for the
15 Liraglutide Safety Committee stored in a central location in the ordinary course of
16 business, it will produce those documents.

17 **REQUEST NO. 58:**

18 All notes, recordings, handouts, materials and presentations YOU or YOUR
19 employees are aware of that were made or obtained in connection with any
20 meeting, conference or other event, internal or external, at which the subject of
21 whether VICTOZA or any other GLP 1 agonist or DPP 4 inhibitor CAUSES and/or
22 is capable of CAUSING pancreatitis and/or pancreatic cancer was discussed.

23 **RESPONSE TO REQUEST NO. 58:**

24 NNI incorporates, as if fully set forth herein, the General Objections by
25 reference. NNI further objects to this Request as overly broad and unduly
26 burdensome. NNI further objects to this Request as vague and ambiguous, as it
27 fails to define key terms, including “meeting,” “conference,” “event,” or
28 “discussed.” NNI further objects to this Request to the extent it seeks documents

1 not in NNI's possession, custody, or control. NNI further objects to the extent that
2 this Request relates to or seeks information regarding products other than
3 Victoza®. NNI further objects to this Request to the extent that it suggests there is a
4 causal connection between Victoza® and pancreatic cancer. NNI further objects to
5 this Request to the extent it seeks "all" notes, recordings, handouts, materials, and
6 presentations on the topic as unduly burdensome and overly broad.

7 Subject to and without waiving or otherwise limiting the foregoing General
8 and Specific Objections, NNI states that responsive documents can be found, to the
9 extent they exist, within the custodial files of key custodians, including, but not
10 limited to, Alan Moses, Jason Brett, and Lotte Knudsen.

11 **REQUEST NO. 59:**

12 If the sale of VICTOZA has ever been prohibited due to concerns that it may
13 CAUSE pancreatitis and/or pancreatic cancer, produce all emails, letters, reports,
14 memoranda and other written communications received by YOU addressing or
15 discussing those concerns, and all emails, letters, reports, memoranda and other
16 written communications prepared by YOU (whether sent or not sent) addressing or
17 discussing those concerns.

18 **RESPONSE TO REQUEST NO. 59:**

19 NNI incorporates, as if fully set forth herein, the General Objections by
20 reference. NNI further objects to this Request as overly broad and unduly
21 burdensome to the extent it seeks all emails, letters, reports, memoranda, and other
22 written communications. NNI further objects to this Request to the extent it seeks
23 documents regarding foreign regulatory activities.

24 Subject to and without waiving or otherwise limiting the foregoing General
25 and Specific Objections, NNI states that the sale of Victoza® has never been
26 prohibited in the U.S. market due to concerns that it may cause pancreatic cancer or
27 pancreatitis.

28 /////

**INCRETIN SCIENCE AND SCIENTIFIC LITERATURE:
BIAS/INFLUENCE/RELIABILITY**

REQUEST NO. 60:

If any of YOUR employees, officers, directors, agents, contractors, key opinion leaders, members of speakers' bureaus, advisory board members, or scientific advisors have corresponded with or supplied information or data to any scientific journal regarding whether VICTOZA or any other GLP 1 agonist or DPP 4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic cancer, produce the correspondence, information and/or data.

RESPONSE TO REQUEST NO. 60:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Request as vague and ambiguous as it fails to define certain terms and phrases, including "key opinion leader," "member of speaker bureau," "advisory board member," and "scientific advisor." NNI further objects to the term "any scientific journal" as overly broad and unduly burdensome. NNI further objects to this Request to the extent it seeks information concerning non-NNI personnel. NNI further objects to this Request to the extent it seeks information regarding products other than Victoza®. NNI further objects to this Request to the extent it seeks information concerning activities outside the United States. NNI further objects to this Request to the extent that it suggests there is a causal connection between Victoza® and pancreatic cancer.

Subject to and without waiving or otherwise limiting the foregoing General and Specific Objections, NNI states that responsive documents can be found, to the extent they exist, within the custodial files of key custodians, including, but not limited to, Alan Moses, Jason Brett, and Lotte Knudsen.

REQUEST NO. 61:

If any of YOUR employees, officers, directors, agents, contractors, key opinion leaders, members of speakers' bureaus, advisory board members, or

1 scientific advisors have submitted a manuscript, case report, article described as an
2 “advertisement,” opinion piece or topic to any scientific journal regarding whether
3 VICTOZA or any other GLP 1 agonist or DPP 4 inhibitor CAUSES and/or is
4 capable of CAUSING pancreatitis and/or pancreatic cancer, produce the material
5 submitted.

6 **RESPONSE TO REQUEST NO. 61:**

7 NNI incorporates, as if fully set forth herein, the General Objections by
8 reference. NNI further objects to this Request as vague and ambiguous as it fails to
9 define certain terms and phrases, including “key opinion leader,” “member of
10 speaker bureau,” “advisory board member,” and “scientific advisor.” NNI further
11 objects to this Request to the extent it seeks information concerning non-NNI
12 personnel. NNI further objects to this Request to the extent it seeks information
13 regarding products other than Victoza®. NNI further objects to the term “any
14 scientific journal” as overly broad and unduly burdensome. NNI further objects to
15 this Request to the extent it seeks information concerning activities outside the
16 United States. NNI further objects to this Request to the extent that it suggests
17 there is a causal connection between Victoza® and pancreatic cancer.

18 Subject to and without waiving or otherwise limiting the foregoing General
19 and Specific Objections, NNI states that responsive documents can be found, to the
20 extent they exist, within the custodial files of key custodians, including, but not
21 limited to, Alan Moses, Jason Brett, and Lotte Knudsen.

22 **REQUEST NO. 62:**

23 If any of YOUR employees, officers, directors, agents, contractors, key
24 opinion leaders, members of speakers’ bureaus, advisory board members, or
25 scientific advisors have participated in or supplied information or data to any expert
26 meeting, panel or committee investigating or reviewing whether VICTOZA or any
27 other GLP 1 agonist or DPP 4 inhibitor CAUSES and/or is capable of CAUSING
28 pancreatitis and/or pancreatic cancer, produce the correspondence, data and other

DOCUMENTS supplied to, received from, or created by such meeting(s), panel(s) or committee proceedings.

RESPONSE TO REQUEST NO. 62:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Request as vague and ambiguous in that it fails to define certain terms and phrases, including “key opinion leader,” “member of speaker bureau,” “advisory board member,” and “scientific advisor,” “investigating or reviewing,” and “expert meeting, panel or committee.” NNI further objects to this Request as overly broad and unduly burdensome to the extent it seeks information related “to any expert meeting, panel or committee.” NNI further objects to this Request to the extent it seeks information concerning non-NNI personnel. NNI further objects to this Request to the extent it seeks information regarding products other than Victoza®. NNI further objects to this Request to the extent it seeks information concerning activities outside the United States. NNI further objects to this Request to the extent that it suggests there is a causal connection between Victoza® and pancreatic cancer.

Subject to and without waiving or otherwise limiting the foregoing General and Specific Objections, NNI states that responsive documents can be found, to the extent they exist, within the custodial files of key custodians, including, but not limited to, Alan Moses, Jason Brett, and Lotte Knudsen.

REQUEST NO. 63:

If any of YOUR employees, officers, directors, agents, contractors, key opinion leaders, members of speakers’ bureaus, advisory board members, or scientific advisors corresponded with or supplied information or data to any authors, medical journals, scientific journals, any other publications, any diabetes research or research funding organizations or persons affiliated with them, any scientific advisors, or any consultants about Dr. Susan Bonner Weir, Dr. Alexandra E. Butler, Dr. Peter C. Butler, Dr. David D. Dore, Dr. Daniel J.

1 Drucker, Dr. Michael Elashoff, Dr. Robert Elashoff, Dr. Edwin Gale, Dr. Rajesh
2 Garg, Dr. Belinda Gier, Dr. Fred Gorlick, Dr. Steven Kahn, Dr. Jacqueline Koehler,
3 Dr. Aleksey V. Matveyenko, Dr. Robert Ratner, Dr. Sonal Singh, or Dr. Jay S.
4 Skyler, and/or about any of the work they have done or authored regarding incretin
5 medications, produce the correspondence, information and/or data.

6 **RESPONSE TO REQUEST NO. 63:**

7 NNI incorporates, as if fully set forth herein, the General Objections by
8 reference. NNI further objects to this Request as vague and ambiguous as it fails to
9 define certain terms and phrases, including “corresponded with or supplied
10 information or data,” “key opinion leader,” “member of speaker bureau,” “advisory
11 board member,” and “scientific advisor.” NNI further objects to the term “any
12 scientific journal” as overly broad and unduly burdensome. NNI further objects to
13 this Request to the extent it seeks information concerning non-NNI personnel. NNI
14 further objects to this Request to the extent it seeks information regarding products
15 other than Victoza®. NNI further objects to this Request to the extent it seeks
16 information unrelated to the alleged risks and injuries at issue in this litigation.
17 NNI further objects to this Request to the extent it seeks information concerning
18 activities outside the United States. NNI further objects to this Request to the
19 extent that it suggests there is a causal connection between Victoza® and pancreatic
20 cancer.

21 Subject to and without waiving or otherwise limiting the foregoing General
22 and Specific Objections, NNI states that responsive documents can be found, to the
23 extent they exist, within the custodial files of key custodians, including, but not
24 limited to Alan Moses, Jason Brett, and Lotte Knudsen.

25 **REQUEST NO. 64:**

26 To the extent not already produced in response to the preceding requests, all
27 emails, letters, reports, memoranda and other written communications with authors,
28 medical journals, scientific journals, any other publications, any diabetes research

1 or research funding organizations or persons affiliated with them, any scientific
2 advisors, or any consultants about whether VICTOZA or any other GLP 1 agonist
3 or DPP 4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or
4 pancreatic cancer.

5 **RESPONSE TO REQUEST NO. 64:**

6 NNI incorporates, as if fully set forth herein, the General Objections by
7 reference. NNI further objects to this Request as overly broad and unduly
8 burdensome to the extent it requests “all” emails, letters, reports, memoranda and
9 other written communications, with multiple enumerated individuals. NNI further
10 objects to the extent that this Request relates to or seeks information regarding
11 products other than Victoza®. NNI further objects to this Request to the extent it
12 seeks information concerning activities outside the United States. NNI further
13 objects to this Request to the extent that it suggests there is a causal connection
14 between Victoza® and pancreatic cancer.

15 Subject to and without waiving or otherwise limiting the foregoing General
16 and Specific Objections, NNI states that responsive documents can be found, to the
17 extent they exist, within the custodial files of key custodians, including, but not
18 limited to Alan Moses, Jason Brett, and Lotte Knudsen.

19 **REQUEST NO. 65:**

20 All DOCUMENTS that constitute or discuss compensation, honoraria,
21 grants, scholarships or gifts, whether offered or actually paid, to individuals or
22 institutions for work (including, without limitation, work done on preclinical
23 studies, nonclinical studies, animal studies, human studies, other research, or the
24 authorship of articles) concerning whether VICTOZA or any other GLP 1 agonist
25 or DPP 4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or
26 pancreatic cancer. Include in YOUR response, without limitation, all such
27 DOCUMENTS pertaining to Dr. Susan Bonner Weir, Dr. David D. Dore,
28 Dr. Daniel J. Drucker, Dr. Rajesh Garg, Dr. Fred Gorlick, Dr. Steven Kahn,

1 Dr. Jacqueline Koehler, Dr. Robert Ratner, Dr. Jay S. Skyler, and/or the companies
2 and/or organizations that employ them.

3 **RESPONSE TO REQUEST NO. 65:**

4 NNI incorporates as if fully set forth herein, the General Objections by
5 reference. NNI further objects to the extent that this Request relates to or seeks
6 information regarding products other than Victoza®. NNI further objects to the
7 extent that this Request seeks documentation not maintained by NNI in the
8 regular and ordinary course of business. NNI further objects to this Request to
9 the extent it seeks documentation related to compensation, honoraria, grants,
10 scholarships or gifts that were not offered or actually paid by NNI or NNI
11 officers, directors, agents, or employees.

12 Subject to and without waiving or otherwise limiting the foregoing General
13 and Specific Objections, NNI states that to the extent responsive information for
14 the individuals identified above can be identified from a reasonable search and
15 retrieved from a central location as kept in the ordinary course of business, NNI
16 will produce responsive information.

17 **DOCUMENT RETENTION, DESTRUCTION AND ARCHIVING**
18 **REQUEST NO. 66:**

19 All of YOUR DOCUMENT retention, destruction and archiving policies that
20 apply to VICTOZA preclinical, nonclinical, animal, human and/or observational
21 studies; other studies addressing, in whole or in part, whether VICTOZA CAUSES
22 and/or is capable of CAUSING pancreatitis and/or pancreatic cancer; VICTOZA
23 ADVERSE EVENTS; and any other DOCUMENTS addressing whether
24 VICTOZA CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic
25 cancer.

26 **RESPONSE TO REQUEST NO. 66:**

27 NNI incorporates as if fully set forth herein, the General Objections by
28 reference. NNI objects to this Request as overly broad and unduly burdensome.

1 NNI further objects to this Request as it is not relevant to general causation issues.

2 Subject to and without waiving or otherwise limiting the foregoing General
3 and Specific Objections, NNI refers Plaintiffs to its SOP production for responsive
4 information, to the extent it exists.

5 **PRIVILEGE LOG**

6 **REQUEST NO. 67:**

7 To the extent that YOU have withheld any DOCUMENTS responsive to any
8 of these requests under any claim of privilege, produce a privilege log as required
9 by Fed. R. Civ. P. 26.

10 **RESPONSE TO REQUEST NO. 67:**

11 At the request of Plaintiffs, a privilege protocol was agreed to be considered
12 and negotiated among the Parties. NNI, in connection with the co-defendants in
13 this litigation, provided Plaintiffs with a draft privilege protocol for review several
14 months ago and have not received a response. NNI objects to producing a privilege
15 log until a protocol is agreed upon.

16 Dated: May 8, 2014

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